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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/027,715 | 12/20/2001 | Robert Kraemer | J&J 2081 | 9750 |
| 27777 | 7590 | 05/04/2004 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | BOGART, MICHAEL G | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/027,715 | Applicant(s) KRAEMER ET AL. | |
| | Examiner Michael G. Bogart | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12, 15, 18, 26, 35-38 and 40-43 is/are rejected.
- 7) ☒ Claim(s) 9-11, 13, 14, 16, 17, 19-25, 27-34 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/20/01; 01/08/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 6 and 30 are objected to because of the following informalities:

Claim 6 recites the limitation "the core *consisting of pressed fibrous material*" in lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 recites the limitation "the microperforated" in line 2. It appears that applicants have omitted "layer" after "microperforated." Also, there is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

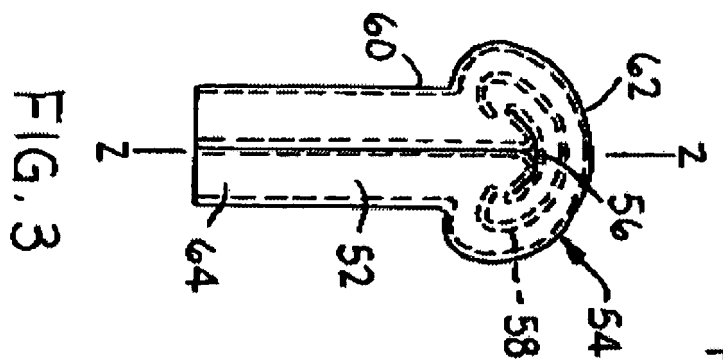
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 12, 15, 35-38 and 43 are rejected under 35 U.S.C. § 102(e) as being anticipated by Zunker *et al.* (US 6,090,098 A).

Regarding claim 1, Zunker *et al.* teach an intravaginal device (50) for feminine hygiene, wherein the intravaginal device (50) comprises a core (52) which is completely surrounded by a sheathing (60) that is impervious liquid water (col. 6, lines 12-58)(see Fig. 3, below).

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Regarding claim 2, Zunker *et al.* teach that the core (52) comprises compressed fibrous material (col. 4, lines 24-48; col. 7, line 66-col. 8, line 13).

Regarding claim 3, Zunker *et al.* teach that the fibrous material consists of natural and/or synthetic fibers (col. 4, lines 24-48).

Regarding claim 4, Zunker *et al.* teach that the fibrous material consists of smooth fibers and/or profiled fibers (24-48).

Regarding claim 5, Zunker *et al.* teach that the fibrous material has least partially hydrophilic properties (col. 4, lines 24-33).

Regarding claim 12, Zunker *et al.* teach that one surface of the sheathing (60) is continuously closed and smooth (col. 6, lines 15-18).

Regarding claim 15, Zunker *et al.* teach that the sheathing (60) comprises at least one plastic film layer (col. 6, lines 51-58).

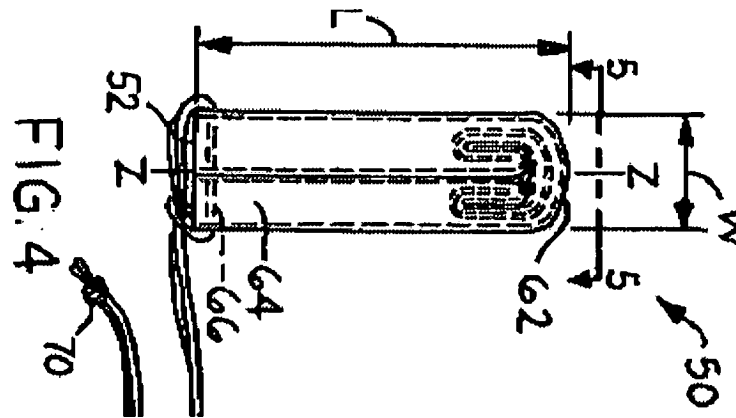
Regarding claim 35, Zunker *et al.* teach that the intravaginal device (50) has a length of about 55 to about 60 mm and a diameter of about 19 about mm (col. 7, lines 25-45).

Regarding claim 36, Zunker *et al.* teach that the intravaginal device (50) is sized to provide support to a user's urinary system (col. 1, line 59-col. 2, line 22).

Regarding claim 37, Zunker *et al.* teach that the device (50) is

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substantially cylindrical (see Fig. 4, below).



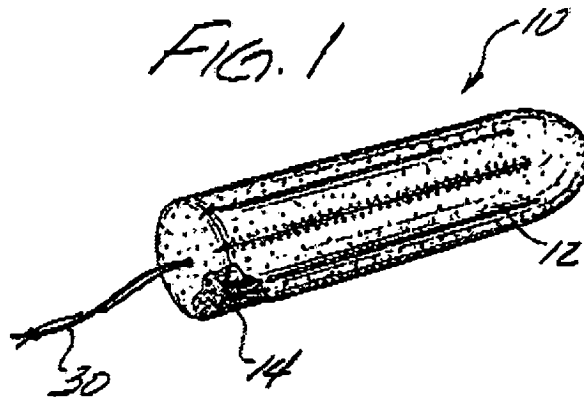
Regarding claim 38, Zunker *et al.* teach a intravaginal device (50) which is substantially ovoid (col. 6, lines 3-11).

Regarding claim 43, Zunker *et al.* teach a device (50) having a conically tapered insertion end (see Fig. 3, above).

Claims 1, 6, 8, 18, 26, 27, 28 and 40 are rejected under 35 U.S.C. § 102(e) as being anticipated by Johnson *et al.* (USPAP 2003/0093049 A1).

Regarding claim 1, Johnson *et al.* teach an intravaginal device (10) for feminine hygiene, wherein the intravaginal device (10) comprises a core (14) which is completely surrounded by a sheathing (12) that is impervious liquid water (Abstract)(Fig. 1, below).

Regarding claim 6, Johnson *et al.* teach that the sheathing (12) is at least partially fastened on the surface of the core consisting of pressed fibrous material (§ 0037 and § 0040).



Regarding claim 8, Johnson *et al.* teach that the sheathing (12) is heat-sealed to the core (14)(¶ 0037 and ¶ 0040).

Regarding claim 18, Johnson *et al.* teaches that the sheathing (12) comprises at least two layers of material which at least partially lie one on top of the other and are bonded to one another (¶ 0021).

Regarding claim 26, Johnson *et al.* teach that the sheathing (12) comprises an at least partially microporous layer (¶ 0015).

Regarding claim 27, Johnson *et al.* teach that the sheathing (12) comprises an at least partially microperforated layer (¶ 0015).

Regarding claim 28, Johnson *et al.* teach that the sheathing (12) comprises a three-layers (¶ 0021).

Regarding claim 40, Johnson *et al.* teach a receptacle portion (14) for collecting bodily discharges.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson *et al.*

Johnson *et al.* fails to expressly teach an embodiment where the sheathing (12) is fastened on the core (14) by means of a contact adhesive (§ 0040).

Johnson *et al.* do teach that heat-sealing and adhesive sealing are mechanically equivalent means of attaching substrates in the relevant art (§ 0003).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute adhesive bonding for the thermal bonding of the core and sheath of Johnson *et al.* in order to provide an attaching means that does not require a heat source.

Claims 41 and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zunker *et al.*

Zunker et al. teaches a resilient member (58) which gives the disclosed device (50) its axial compressive resistance.

Zunker et al. teaches the claimed invention except for the specific value of its axial compressive resistance of the device.

Generally, optimization of ranges alone is not sufficient to patentably distinguish an apparatus over the prior art. *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969), *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP § 2144.05 (II).

In the present case, increasing or decreasing the resilience of the member (58) taught by *Zunker et al.* will cause a directly corresponding increase or decrease in the amount of force required to axially compress the device (50). Axial compressibility of the device is therefore a result effective variable. At the time of the invention, it would have been obvious to one of ordinary skill in the art to optimize the resiliency of the device of *Zunker et al.* in order to achieve a balance between comfort and the ability of the device to stay in place on a user.

Allowable Subject Matter


Claims 9-11, 13, 14, 16, 17, 19-20, 27-34 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (703) 605-1184. The examiner can normally be reached Monday-Friday.

In the event the examiner is not available, the examiner's supervisor, John Calvert may be reached at phone number (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 746-3380 for informal communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.


Michael Bogart
28 April 2004


JOHN J. CALVERT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700